IN THE UNITED STATES OF AMERICA
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Carmen Purl, M.D.; and Carmen Purl, M.D., PLLC d/b/a Dr. Purl's Fast Care Walk In Clinic, *Plaintiffs*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; Office for Civil Rights of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*, and City of Columbus, Ohio; City of Madison, Wisconsin; and Doctors for America, *Intervenor-Defendants*.	Civil Action No. 2:24-cv-228-Z

[PROPOSED] MEMORANDUM OF LAW IN SUPPORT OF INTERVENOR-DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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The cities of Columbus, Ohio, and Madison, Wisconsin, together with Doctors for America, having moved for leave to intervene as defendants to protect their legal interests in upholding the two regulations at issue in this case pursuant to Fed. R. Civ. P. 24 ("Intervenor-Defendants"), by and through their undersigned counsel, respectfully submit this memorandum of law in support of their motion for summary judgment against the above-captioned action in its entirety pursuant to Fed. R. Civ. P. 56(a), and adopt and join in Defendants' arguments in support of, and motion for, summary judgment, except as to standing. *See* Dkts. 39–40.

PRELIMINARY STATEMENT

Plaintiffs' Complaint challenges rules that protect the confidentiality, use, and disclosure of patient health information involving lawful reproductive care. The confidentiality of patient health information that Plaintiffs seek to undermine is a cornerstone of effective health care and is governed by statute, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936. Patients and clinicians alike rely on the protections afforded by HIPAA to use and disclose information regarding patient health care efficiently, effectively, and confidentially. HIPAA and its implementing regulations (the "Privacy Rules") ensure that patient information—including sensitive information touching on the patient's symptoms, questions, fears, diagnoses, prognoses, test results, images, treatment, medical history, medication, wishes, and bills—remains confidential. When patient information does need to be disclosed for certain non-health care purposes, the Privacy Rules ensure that information remains confidential, too.

The Complaint targets a final rule promulgated by the Department of Health and Human Services ("HHS" or the "Department") in 2024 pursuant to Congress's express delegation of authority in the HIPAA statute. *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*,

89 Fed. Reg. 32976 (Apr. 26, 2024) (the "2024 Rule" or the "Rule"). The 2024 Rule strengthens protections for patient information involving lawful reproductive care, which can be particularly sensitive and is uniquely jeopardized by recent uncertainty arising from changes in law and the divergence of law between and among states. The Department promulgated the 2024 Rule consistent with the statutory authority expressly delegated to it by Congress in HIPAA. Congress directed the Department to "promulgate final regulations" containing "standards with respect to the privacy of individually identifiable health information," including specifically as pertains to the "rights that an individual who is a subject of individually identifiable health information should have," "[t]he procedures that should be established for the exercise of such rights," and "[t]he uses and disclosures of such information that should be authorized or required," Appx. 561 (42 U.S.C. § 1320-d note) (codifying Pub. L. 104-191, title II, § 264)), and to "adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320-d-3(b)(1). In promulgating the 2024 Rule, the Department considered the relevant factors and acted well within its discretion.

The 2024 Rule does not impede legitimate law enforcement. The Privacy Rules expressly provide exceptions to confidentiality when law enforcement has a legitimate basis to obtain confidential information and engages in the appropriate process. Under the 2024 Rule, law enforcement continues to be able to access protected health information, *including* reproductive health care information, pursuant to these exceptions as long as the disclosure is not sought for the prohibited purpose of imposing criminal, civil, or administrative investigation or liability on someone for merely seeking, obtaining, providing, or facilitating lawful reproductive health care. If law enforcement needs reproductive health care information for a different, legitimate reason, it can request the information pursuant to other, permissible exceptions in the Privacy Rules, and, where

necessary, include an attestation that it is not seeking the information in order to punish the mere act of seeking or providing legal care. Intervenor-Defendants, and the constituencies they represent and serve as municipalities or as clinicians, are subject to and impacted by the 2024 Rule as detailed in their motion to intervene, as are all participants in the health care system who depend upon the 2024 Rule as a critical part of the framework governing the transmission, maintenance, access, and disclosure of individually identifiable information regarding reproductive health care.

Enjoining and setting aside the 2024 Rule, as Plaintiffs demand, would be devastating for patients, providers, cities, and all those who participate in the health care system. In seeking that relief, the Complaint disregards both the text of the HIPAA statute directing the Department to implement the rules, and the text of the Rules as issued. Plaintiffs offer no meaningful argument that the 2024 Rule violates the Administrative Procedure Act, but rather ask this Court to substitute its judgment for Congress's duly-enacted legislation and the 2024 Rule to limit the protections afforded to reproductive health care nationwide.

Plaintiffs' Complaint fails as a matter of law because it disregards the will of Congress as represented by the text of the governing HIPAA statute, the context in which it was enacted, and the text of the 2024 Rule. The Complaint ignores (although it does not dispute) the Department's consideration of relevant factors when promulgating the 2024 Rule, and disregards the legal standards applicable to its claims. Plaintiffs cannot overcome the stark record demonstrating as a matter of law that the 2024 Rule was issued consistent with the Department's statutory authority and is not arbitrary and capricious.

For the reasons stated below and in the brief of the Department of Health and Human Services and individual Defendants (collectively, "Defendants"), this Court should dismiss Plaintiffs'

Complaint in its entirety, and enter judgment for the Defendants. Intervenor-Defendants also incorporate and rely upon Defendants' responses to the Court's December 22, 2024 Order requesting the parties to address questions not raised on the face of the Complaint. *See* Dkt. 40 at 10 n.1.

BACKGROUND

The relevant background is set forth in detail in the Defendants' Brief and summarized here.

In 1996, Congress enacted HIPAA to "improve the efficiency and effectiveness" of health care, in part by "establish[ing] standards and requirements for the electronic transmission of certain health information." Appx. 549 (42 U.S.C. § 1320d note (codifying Pub. L. 104–191, title II, § 261)). Congress instructed HHS to adopt uniform standards "to enable health information to be exchanged electronically." 42 U.S.C § 1320d-2(a)(1). That direction encompassed instructions to adopt uniform standards regarding the electronic exchange of health information, *id.* § 1320d-2(a), unique identifiers for participants in the health care system, *id.* § 1320d-2(b), standards for transactions and data relating to health information, *id.* § 1320d-2(a), and the security of health care information, *id.* § 1320d-2(d). Congress also expressly considered the need to adopt standards protecting the privacy of health information maintained under HIPAA and, in Section 264(a), directed HHS to submit to Congress "detailed recommendations on standards with respect to the privacy of individually identifiable health information." Appx. 561 (42 U.S.C § 1320d-2 note). As required by the Act, the Department transmitted these recommendations to Congress within 12 months, on September 11, 1997. *Id.*; 42 U.S.C. § 1320d-2(a)(1); Appx. 012 (65 Fed. Reg. at 82470 (Dec. 28, 2000)).

Congress provided that if it did not enact legislation establishing these standards within 36 months after HIPAA's enactment, "the Secretary of Health and Human Services shall promulgate final regulations containing such standards." Appx. 561 (42 U.S.C. § 1320d–2 note). Further,

Congress directed the Secretary to "review the standards" and "adopt modifications to the standards (including additions . . .), as determined appropriate." 42 U.S.C. § 1320d–3. Congress included an express preemption provision, mandating that "a provision or requirement under [HIPAA], or a standard or implementation specification adopted under [HIPAA] . . . , shall supersede any contrary provision of State law," with limited exceptions, including for "public health." 42 U.S.C. § 1320d-7(a)(1), (b). In its preemption provision, Congress made clear that the privacy regulations to be promulgated by HHS would constitute a floor nationwide, preempting and superseding less stringent protections, but not contrary provisions of state law that may be "more stringent" than the requirements of HHS's HIPAA rules. Appx. 561–62 (42 U.S.C. § 1320d-2 note).

In 2000, after Congress did not enact legislation within the 36-month period, the Department proposed and ultimately promulgated regulations about medical privacy: the Standards for Privacy of Individually Identifiable Health Information. *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164); Appx. 12 (65 Fed. Reg. at 82470 (Dec. 28, 2000) ("2000 Privacy Rule")). The 2000 Privacy Rule established a set of national standards for protecting certain health information. *See* 45 C.F.R. § 164.502; Appx. 6 (65 Fed Reg at 82464 (Dec. 28, 2000)). This included "general rules" for the use and disclosure of protected health information ("PHI"), as well as rules establishing individuals' rights regarding their PHI and listing specific circumstances when a covered entity is permitted to use or disclose PHI without an individual's consent. *See* 45 C.F.R. § 164.512; Appx. 378 (89 Fed Reg at 32982 (Apr. 26, 2024)). The Department has continuously administered and updated the Privacy Rule since 2000. Appx. 373 (89 Fed. Reg. at 32977 (Apr. 26, 2024)).

The 2024 Rule that is the target of Plaintiffs' Complaint was promulgated after the Department proposed to amend the 2000 Privacy Rule to address more recent developments, consistent with the principles and policy set forth by Congress in HIPAA and following an iterative rulemaking process that the statute expressly contemplated and authorized. *See* 42 U.S.C. § 1320d-3(b)(1) ("[T]he Secretary shall review the standards adopted under section 1320d–2 of this title, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate . . . "); Appx. 377 (89 Fed. Reg. at 32981 (Apr. 26, 2024) ("Congress contemplated that the Department's rulemaking authorities under HIPAA would not be static. Congress specifically built in a mechanism to adapt such regulations as technology and health care evolve . . . ")) (citing 42 U.S.C. § 1320d-3). The Department consulted with federal and state agencies and the National Committee on Vital and Health Statistics, and considered more than 25,900 comments, before promulgating the Privacy Rule To Support Reproductive Health Care Privacy (the 2024 Rule). Appx. 372, 374, 387 (89 Fed. Reg. at 32976, 32978, 32991 (Apr. 26, 2024)). The 2024 Rule's purpose is to "amend provisions of the [2000] Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." *Id.* at 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). This rule went into effect on June 25, 2024. *Id.* at 372 (89 Fed. Reg. at 32976 (Apr. 26, 2024)).

Plaintiffs assert that the 2024 Rule interferes with their ability to "comply with all required and permissive abuse reporting under state law, and . . . state administrative requests authorized by state law," Compl. ¶ 97, and requires them to incur certain "compliance costs," *id*. at ¶¶ 9, 99–102.

PROCEDURAL HISTORY

On October 21, 2024, Plaintiffs brought suit against the Department, the Department's Secretary Xavier Becerra, the Department's Office for Civil Rights, and the Department's Director of the Office for Civil Rights, Melanie Fontes Rainer, alleging two counts under the Administrative Procedure Act ("APA"): that, by promulgating the 2024 Rule, Defendants purportedly exceeded their statutory jurisdiction or authority per 5 U.S.C. § 706(2)(C) (Count I), and acted in a manner that was arbitrary and capricious per 5 U.S.C. § 706(2)(A) (Count II). On November 12, 2024, Plaintiffs sought to preliminarily enjoin the 2024 Rule. *See* Dkt. 24. Defendants opposed on December 3, and Plaintiffs replied on December 10. *See* Dkts. 29, 31.

On December 22, the Court granted Plaintiffs' motion and preliminarily enjoined Defendants from enforcing the 2024 Rule against Plaintiffs during the remainder of this suit. *See* Dkt. 34 at 22. The Court also ordered the parties to submit summary judgment briefing, as well as supplemental briefing addressing questions raised by the Court regarding the constitutionality or legality of HIPAA and HHS's authority to issue the 2024 Rule, as well as on whether the Rule's definition of "reproductive health care" is void for vagueness. *See id*. at 21–22. On January 6, 2024, the Court ordered a modified briefing schedule and requested dispositive motions on or before January 17, 2025. *See* Dkt. 38. On that date, Intervenor-Defendants filed their Motion to Intervene, seeking to protect their interests and to be heard regarding the sweeping relief that the Plaintiffs seek, including by moving for summary judgment and dismissal as to both counts of the Complaint under Fed. R. Civ. P. 56(a).

ARGUMENT

Summary judgment should be granted when "there is no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). It is the movant's burden to demonstrate "the absence of a genuine issue of material fact," and entry of summary judgment is required against any party "who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Jones v. United States*, 936 F.3d 318, 321 (5th Cir. 2019) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994)).

As Defendants establish in their opening brief, Congress expressly delegated rulemaking authority to the Department under HIPAA and the 2024 Rule is squarely within the scope of that delegated statutory authority and valid under the APA. *See* 5 U.S.C. § 706(2)(A). Under the APA, an agency's action must be upheld unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or is in excess of statutory authority. *Id*. § 706(2)(A), (C). In reviewing a claim under the APA, the Court is to presume the agency's action is valid and is to consider only whether that action "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The Court's review is "neither sweeping nor intrusive." *Fort Bend Cnty. v. U.S. Army Corps of Eng'rs*, 59 F.4th 180, 194 (5th Cir. 2023) (citing *Amin v. Mayorkas*, 24 F.4th 383, 393 (5th Cir. 2022)). The Court may not "substitute its judgment for that of the agency." *Overton Park*, 401 U.S. at 416; *see also Barr v. Sec. & Exch. Comm'n*, 114 F.4th 441, 447 (5th Cir. 2024) ("Agency decisions are 'presumptively valid; the [petitioner] bears the burden of showing otherwise.'") (quoting *Tex. Tech Physicians Assocs. v. U.S. Dep't of Health & Hum. Servs.*, 917 F.3d

837, 844 (5th Cir. 2019) (brackets in original)). When Congress statutorily grants an agency with authority and discretion to propose and enact rules, the agency's discretion is notably broad. *Little Sisters of the Poor v. Pennsylvania*, 591 U.S. 657, 677 (2020) (agency has broad discretion to craft guidelines when granted on the face of the statutory text).

Plaintiffs cannot satisfy this high legal standard for their claims, or overcome the presumption that the agency action was valid. They maintain that the Department lacks the authority to promulgate new rules limiting how regulated entities share information with state governments, and seek to set those rules aside in favor of allowing them to divulge reproductive health care information to the state absent the safeguards the 2024 Rule proscribes. *See* Compl. ¶¶ 114–27 (Count 1). That Plaintiffs disagree with the policy enacted by Congress in HIPAA and followed by the Department in enacting the 2024 Rule is not a sufficient legal basis for relief under the APA. The Department's issuance of the 2024 Rule falls squarely within its authority and discretion, and summary judgment is warranted with respect to Plaintiffs' claims, for the reasons set forth in Defendants' January 17, 2025 brief and motion.

As Defendants demonstrate, the Department's authority, and appropriate exercise of discretion, are clear on the record. On its face, HIPAA expressly authorizes the Secretary to "review" and "adopt modifications to the standard . . . as deemed appropriate," 42 U.S.C. § 1320d-3(b)(1), and that is precisely what the Department did when it issued the 2024 Rule. The Rule provides that "a covered entity or business associate may not use or disclose protected health information . . . [t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care," or to impose "criminal, civil, or administrative liability" for the same. 45 C.F.R. § 164.502(a)(5)(iii). The 2024 Rule is consistent

with HIPAA's purpose "to improve the efficiency and effectiveness of the health care system, which includes ensuring that individuals have trust in the health care system," Appx. 385 (89 Fed. Reg. at 32989 (Apr. 26, 2024)), and "directly advances the purposes of HIPAA by setting minimum protections for PHI" with respect to reproductive care, "thereby improving the effectiveness of the health care system by ensuring that persons are not deterred from seeking, obtaining, providing, or facilitating reproductive health care," *id.* at 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)).

The Rule does not run afoul of the statutory mandate that HIPAA does not invalidate or limit "reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b). The Rule does not prohibit disclosures of PHI where the request is to lawfully investigate a matter of public health, consistent with 42 U.S.C. § 1320d-7(b), *see* Appx. 388–90, 394 (89 Fed. Reg. at 32992–94, 98 (Apr. 26, 2024)), and it maintains the existing provisions permitting use and disclosure for public health oversight activities. 45 C.F.R. § 164.512(b), (c). The 2024 Rule does not prohibit disclosure in connection with child abuse reporting or ***unlawful*** provision of reproductive health care, *see id.* § 164.502(a)(5)(iii)(B), again consistent with Congress's directive. The defined terms used in the 2024 Rule are neither vague nor ambiguous, but clearly specified and consistent with plain meaning and prior use—again, as Defendants demonstrate. In adopting such definitions and promulgating the Rule, the Department acted well within its discretion and authority, including for the reasons Defendants argue in their January 17, 2025 submission.

On this undisputed record, Plaintiffs cannot show that the Department engaged in action beyond its authority or that was "arbitrary, capricious, [or] an abuse of discretion" when promulgating the 2024 Rule. 5 U.S.C. § 706(2)(C); *see Barr*, 114 F. 4th at 447 ("Agency decisions

are presumptively valid; the petitioner bears the burden of showing otherwise.") (cleaned up); *Associated Builders & Contractors of Texas, Inc. v. Nat'l Lab. Rels. Bd.*, 826 F.3d 215, 224–25 (5th Cir. 2016) ("To affirm an agency's action, we need only find a rational explanation for how the [agency] reached its decision."); *Huawei Techs. USA, Inc. v. Fed. Commc'ns Comm'n*, 2 F.4th 421, 434 (5th Cir. 2021). Plaintiffs cannot satisfy their burden with respect to the 2024 Rule, and their claims should be dismissed in their entirety and judgment entered for Defendants.

Intervenor-Defendants join in and adopt Defendants' responses to the issues the Court seeks to raise by its December 22, 2024 Order, set forth in Defendants' brief dated January 17, 2025.

CONCLUSION

For the foregoing reasons and those set forth by Defendants in support of their motion to dismiss or in the alternative for summary judgment, *see* Dkt. 40, and the administrative record cited therein, and incorporated herein except as to Defendants' standing argument, the Court should enter judgment and dismiss the above-captioned action in its entirety pursuant to Fed. R. Civ. P. 56(a).

Date: January 17, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

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